

REMARKS

Claims 1-20 currently are pending. Claims 1-4, 6, 10 and 14 currently have been amended.

Claim 1 is objected to because the examiner believes the claim is drawn to a non-elected product: SEQ ID NO: 3.

Applicants believe claim 1 is not drawn to a non-elected product because SEQ ID NO: 3 is the same as SEQ ID NO: 1 except that it contains a 3'-5'-UTR. This untranslated region does not qualify SEQ ID NO: 3 as a separate invention.

Applicants herein amend claims 2 and 14 to remove the examiner's stated informalities.

The examiner objected to claims 2 and 3 because they are drawn to nonelected products Acyl-coA dehydrogenases, Acyl-ACP desaturase, Acyl-ACP thioesterases, fatty acid acyltransferases, fatty acid synthases, fatty acid hydroxylases, acetyl-coenzyme A carboxylases, acyl-conenzyme A oxidases, fatty acid acetylenases, lipoxygenases, triacylglycerol lipases, allenoxide synthases, hydroperoxide lyases, and/or fatty acid elongases, fatty acid acyltransferases, 5-desaturase, 6 desaturase, 9 desaturase, 12-desaturase, 15-desaturase and a fatty acid elongase.

Applicants believe the examiner's objections are improper. The sequences of the fatty acid synthesis recited in claims 2 and 3 are elected products because they specify the nucleic acid sequence part of the fusion protein stemming from the fatty acid biosynthesis or the lipid metabolism claimed in claim 1.

The examiner objected to claim 9 because it recites an "IS element" without providing its

expansion.

Applicants believe the recitation of "IS element" in claim 9 is not improper. As one of ordinary skill in the art knows, IS (insertion sequence) elements are one of the simplest transposable genetic elements found in prokaryotes which are capable of inactivating a gene into which it inserts. In general, insertion sequences have an approximate length of 1000 bases. They are flanked by a short run of inverted repeated sequences at its termini. It is a mobile segment of DNA that contains only genes required for the process of insertion of DNA segment into a chromosome and for the mobilization of the element to different locations. Therefore, applicants do not believe further definition of expansion is required.

The examiner rejected claims 6 and 10-14 under 35 USC § 101 because they are directed to non-statutory subject matter. In response, applicants amend claim 10 to overcome the examiner's rejection.

Claims 1, 2-4, 6, 8-9 and 10-14 are rejected under 35 USC § 112, second paragraph, as being indefinite. The examiner believes the phrase "composed of a combination" is unclear. In response, applicants amend claim 1.

The examiner believes the metes and bounds of the term "derivatives" is unclear. Applicants disagree. The definiteness of the language employed must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art."). *In re Moore*, 58 C.C.P.A. 1042, 439 F.2d 1232, 1235, 169 U.S.P.Q. (BNA) 236, 238 (CCPA 1971). "Derivatives" is defined clearly in the specification on page 6, lines 36-47 and

page 7, lines 1-27.

The examiner believes the phrase "a sequence of the following protein groups" is unclear. The definiteness of the language employed must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art."). *In re Moore*, 58 C.C.P.A. 1042, 439 F.2d 1232, 1235, 169 U.S.P.Q. (BNA) 236, 238 (CCPA 1971). This phrase is defined in the specification on page 10, lines 5-20.

Applicants amend claims 2 and 3 by deleting "gene." This amendment should make clear that applicants refer to a nucleic acid sequence.

Applicants amend claim 4 to recite derivatives with 80% homology to SEQ ID NO: 2. 70% and 90% homologies have been deleted from claim 4. Applicants also delete "Program Pilp.J. Evolution" from claim 4.

Claims 1-4, 6 and 8-14 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the invention. The examiner believes the specification discloses only a single species of the claimed genus (i.e. a polypeptide of SEQ ID NO: 2 having lipid body lipxygenase activity) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus including the fusion proteins. Claims 1-4, 6 and 8-14 are rejected under 35 USC § 112, first paragraph, because the specification, while enabling for a polynucleotide encoding a fusion protein comprising the LBLOX of SEQ ID NO: 2 and the fatty

acid/lipid metabolism enzyme, delta-4-desaturase, wherein the fusion polypeptide continues to have LBLOX activity, does not reasonably provide enablement for a polynucleotide comprising any polynucleotides encoding any enzyme involved in fatty acid/lipid metabolism and a variant or mutant of SEQ ID NO: 1 encoding a polypeptide having at least 60%, 70%, 80% or 90% amino acid sequence identity to SEQ ID NO: 2, wherein the encoded polypeptide of SEQ ID NO: 1 has any function or no function at all, vectors and transformed host cells comprising above.

Summary

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, eg., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.2d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003).

Applicants believe one of ordinary skill in the art would be able to arrive at sequences having 80 % homology to the disclosed sequences. Applicants point to the specification on page 7, lines 20-27 which cite the percent homologies. Also, one of ordinary skill in the art can use available computer programs with accepted algorithms to arrive at the 80% homologous sequences. These are PileUp, BESTFIT, Gap, TRANSLATE and BACKTRANSLATE (=part of the program package UWGCG, Wisconsin Package, Version 10.0-UNIX, January 1999, Genetics Computer Group, Inc., Deverux et al., Nucleic. Acid Res., 12, 1984: 387-395) (J. Mol. Evolution., 25, 351-360, 1987, Higgins et al. CABIOS, 5 1989: 151-153) (specification on page 7 lines 14-20).

In view of the above, applicants request reconsideration of the examiner's position and

withdrawal of the 35 USC § 112, first paragraph rejections.

Claims 1-4, 6, 8-9 and 10-14 are rejected under 35 USC § 103(a) as being obvious.

To establish *prima facie* obviousness, the examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (*see, e.g., In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

Applicants believe the examiner has not met the above requirements and therefore has failed to establish a *prima facie* case of obviousness.

Applicants' invention is related to a method of targeting proteins involved in lipid or fatty acid biosynthesis into liposomes or lipid bodies (see specification, lines 4-7).

Kindl et al. teach a lipid body lipoygenase and its localization in the cell. Kindl et al. disclose nothing about a process for targeting fusion proteins as presently claimed. Kindl is silent about this method. The other cited references do not teach or suggest the present claims either.

Ohlrogge et al. disclose a polynucleotide encoding a delta-4-desaturase and its function in the fatty acid biosynthesis chain. Here again, nothing is disclosed about targeting this enzyme nor a combination of the enzyme and the claimed sequence. Ohlrogge et al. alone, or in combination with the other cited references does not make the present claims obvious.

Yamamoto et al. is related to a method of producing peptides or proteins which makes it

possible to cause a wide range of host microorganisms to produce heterologous fusion proteins and then excise the desired gene products efficiently from the fusion proteins using a highly specific enzyme. Yamamoto et al. is silent about a method for the targeting of proteins as presently claimed.

Therefore, none of the references, standing or alone in combination, teach or suggest the rejected claims.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner and the rejection under 35 USC § 103 should be withdrawn.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 14-1437. Please credit any excess fees to such deposit account.

Respectfully submitted,

NOVAK DRUCE DeLUCA & QUIGG, LLP

A handwritten signature in black ink, appearing to read "Daniel Kim", with a stylized flourish at the end.

Daniel S. Kim

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Respectfully submitted,

NOVAK DRUCE DeLUCA & QUIGG, LLP

A handwritten signature in black ink, appearing to read "Daniel Kim", written in a cursive style.

Daniel S. Kim

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